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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,093	05/10/2001	Preeti G. Lal	PF-0357-1 DIV	8489

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,093

Applicant(s)

LAL ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 9/31/03
- 9/31/03
- I. Claims 1-4, drawn to polypeptides, classified in Class 530, subclass 350 and 514.
 - II. Claims 5-7, 10 and 11, drawn to polynucleotides and compositions containing same, classified in Class 536, subclass 23.1; Class 435, subclasses 243, 320.1, and 325; and Class 514, subclass 44.
 - III. Claim 8, drawn to methods of expression of polypeptides, classified in Class 435, subclass 69.1.
 - IV. Claims 9, 19 and 20, drawn to an antibody, classified in Class 530, subclass 387.1.
 - V. Claims 12 and 13, drawn to a method of detecting a nucleic acid by hybridization, classified in class ~~436~~⁴³⁵, subclass 6.
 - VI. Claim 14, drawn to a method of detecting a nucleic acid by polymerase chain reaction, classified in class ~~436~~⁴³⁵, subclass 6.
 - VII. Claim 15, drawn to a method of screening and detecting agonist compound activity using a polypeptide, classified in class 435, subclass 7.1.
 - VIII. Claim 16, drawn to a method of screening and detecting agonist compound activity using a polypeptide, classified in class 435, subclass 7.1.
 - IX. Claim 17, drawn to a method of screening compounds that alter the expression of a nucleic acid, classified in class 435, subclass 6.
 - X. Claim 18, drawn to a method of testing compound toxicity, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, III, VII and VIII); Groups (II, V, VI, IX and X); and Group IV are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, III, VII and VIII the critical feature is a polypeptide; for Groups II, V, VI, IX and X the critical feature is nucleic acid; and for Group IV the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide

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of the above Groups to be directed as to its synthesis by a polynucleotide of the above Groups, however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I, III, VII and VIII); (II, V, VI, IX and X); and (IV) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups III, VII and VIII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the polypeptides of Group I can be used in the distinct processes of the inventions of Groups III, VII and VIII in therapeutic processes to replace a missing protein, or, alternatively, the activity of a protein can be utilized in an industrial process for chemical processing.

The inventions of Group II and Groups V, VI, IX and X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the nucleic acids of Group II can be used in the distinct processes of the inventions of Groups V, VI, IX and X. One use is directed to polypeptide expression and the other to screening via nucleic acid binding reactions. Alternatively, the nucleic acids of Group II can be used in antisense therapy which is also a clearly distinct usage of such nucleic acids.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 1 P.M to 8 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 10, 2003

Monika B. Sheinberg
Art Unit 1634

MBS

Jehanne Souaya

**JEHANNE SOUAYA
PATENT EXAMINER**

3/11/03